

CHAPTER 3

SECTION 5.3

HEART TRANSPLANTATION

Issue Date: December 11, 1986

Authority: [32 CFR 199.4\(e\)\(5\)\(v\)](#)

I. PROCEDURE CODE

33945, 33975, 33976, 33977, 33978

II. POLICY

A. For beneficiaries who reside in TRICARE regions, benefits are allowed for heart transplantation.

1. A TRICARE Prime enrollee must have a referral from his/her Primary Care Manager (PCM) and an authorization from the Health Care Finder (HCF) before obtaining transplant-related services. If network providers furnish transplant-related services without prior PCM referral and HCF authorization, penalties will be administered according to TRICARE network provider agreements. If Prime enrollees receive transplant-related services from non-network civilian providers without the required PCM referral and HCF authorization, Managed Care Support (MCS) contractors shall reimburse charges for the services on a Point of Service basis. Special cost-sharing requirements apply to Point of Service claims. For specific information on Point of Service cost-shares and catastrophic cap calculations, see [Chapter 12, Section 2.2](#), and [Section 10.1](#), and [Chapter 13, Section 14.1](#).

2. For Standard and Extra patients residing in a Managed Care Support (MCS) region, preauthorization authority is the responsibility of the MCS Medical Director, Health Care Finder, or other designated utilization staff.

B. The designated preauthorizing authority shall only use the criteria contained in this policy when preauthorizing heart transplantation.

C. Affirmative Patient Selection Criteria. Benefits may be allowed for medically necessary services and supplies related to heart transplantation when the transplant is performed at a TRICARE or Medicare approved transplant center, for beneficiaries who:

1. Have an end-stage cardiac disease which has not responded to or no longer responds to other appropriate medical and surgical therapies which might be expected to yield both short and long-term (3 to 5 year) survival comparable to that of heart transplantation; and

2. Has a very poor prognosis as a result of poor cardiac functional status (e.g., less than a 25 percent likelihood of survival for six months); and

3. Have plans for long-term adherence to a disciplined medical regimen are feasible and realistic.

D. Benefits may be allowed for medically necessary services and supplies related to heart transplantation for:

1. Evaluation of a potential candidate's suitability for heart transplantation whether or not the patient is ultimately accepted as a candidate for transplantation.

2. Pre- and post-transplant inpatient hospital and outpatient services.

3. Pre- and post-operative services of the transplant team.

4. The donor acquisition team, including the costs of transportation to the location of the donor organ and transportation of the team and the donated organ to the location of the transplantation center.

5. The maintenance of the viability of the donor organ after all existing legal requirements for excision of the donor organ have been met.

6. Blood and blood products.

7. FDA approved immunosuppression drugs to include off-label uses when determined to be medically necessary and provided in accordance with nationally accepted standards of practice in the medical community (i.e., proven).

8. Complications of the transplant procedure, including inpatient care, management of infection and rejection episodes.

9. Periodic evaluation and assessment of the successfully transplanted patient.

10. Cardiac rehabilitation as outlined in [Chapter 1, Section 18.4](#).

E. Benefits may be allowed for DNA-HLA tissue typing in determining histocompatibility.

III. POLICY CONSIDERATIONS

A. The designated preauthorizing authority must take the following conditions into consideration when determining medical necessity or appropriateness:

1. Advancing age (because of diminished capacity to withstand postoperative complications). The selection of any patients for transplantation beyond age 50 must be done with particular care to ensure an adequately young physiologic age and the absence or insignificance of coexisting disease.

2. Severe pulmonary hypertension (because of the limited work capacity of the typical donor right ventricle). A pulmonary vascular resistance above 5 Wood units or pulmonary artery systolic pressure over 65 mm Hg is considered to be severe pulmonary hypertension.
3. Renal or hepatic dysfunction not explained by the underlying heart failure and not deemed reversible (because of the nephrotoxicity and hepatotoxicity of cyclosporin).
4. Acute severe hemodynamic compromise at the time of transplantation if accompanied by compromise or failure of a vital end-organ (because of a substantially less favorable prognosis for survival than for the average transplant recipient).
5. Symptomatic peripheral or cerebrovascular disease (because of accelerated progression in some patients after cardiac transplantation and chronic corticosteroid treatment).
6. Chronic obstructive pulmonary disease or chronic bronchitis (because of poor postoperative course and likelihood of exacerbation of infection with immunosuppression).
7. Active systemic infection (because of the likelihood of exacerbation with initiation of immunosuppression).
8. Recent and unresolved pulmonary infarction or pulmonary roentgenographic evidence of infection or of abnormalities of unclear etiology (because of the likelihood that this represents pulmonary infection).
9. Systemic hypertension, either at transplantation or prior to development of end-stage cardiac disease, that requires multi-drug therapy for even moderate control (multi-drugs to bring diastolic pressure below 105 mm Hg).
10. Other systemic disease considered likely to limit or preclude survival and rehabilitation after transplantation.
11. Cachexia, even in the absence of major end-organ failure (because of the significantly less favorable survival of such patients).
12. The need for or prior transplantation of a second organ such as lung, liver, kidney, or marrow (because this represents the coexistence of significant disease).
13. A history of a behavior pattern or psychiatric illness considered likely to interfere significantly with compliance with a disciplined medical regimen (because a lifelong medical regimen is necessary, requiring multiple drugs several times a day, with serious consequences in the event of their interruption or excessive consumption).
14. The use of a donor heart, the long-term effectiveness of which might be compromised by such actions as the use of substantial vasopressors prior to its removal from the donor, its prolonged or compromised maintenance between the time of its removal from the donor and its implantation into the patient, or pre-existing disease.

15. Insulin-requiring diabetes mellitus (because the diabetes is often accompanied by occult vascular disease and because the diabetes and its complications are exacerbated by chronic corticosteroid therapy).

16. Asymptomatic severe peripheral or cerebrovascular disease (because of accelerated progression in some patients after cardiac transplantation and chronic corticosteroid treatment).

17. Peptic ulcer disease (because of the likelihood of early postoperative exacerbation); and

18. Current or recent history of diverticulitis (considered as a source of active infection which may be exacerbated with the initiation of immunosuppressant therapy).

B. Services and supplies that may be cost-shared are limited to those listed in [32 CFR 199.4\(e\)\(5\)\(v\)\(B\)](#).

C. Benefits will only be allowed for transplants performed at a TRICARE or Medicare approved heart transplantation center. Additionally, the HeartMate® IPLVAS will be covered only at a TRICARE or Medicare approved heart transplantation center. The contractor in whose jurisdiction the center is located is the certifying authority for TRICARE authorization as a heart transplantation center. Refer to [Chapter 11, Section 11.5](#) for specific criteria heart transplantation centers must meet for TRICARE authorization.

D. Benefits will not be allowed for procedure code 33960, prolonged extracorporeal circulation for cardiopulmonary insufficiency, as this procedure is not considered a bridge assist device.

E. For beneficiaries who reside in TRICARE regions, preauthorization and retrospective authorization of heart transplantation must meet the following two requirements.

1. Patient meets (or as of the date of transplantation, would have met) patient selection criteria; and

2. Transplant facility is (or as of the date of transplantation, would have been) TRICARE or Medicare approved for heart transplantation at the time of transplant.

F. For beneficiaries who reside in TRICARE regions but fail to obtain preauthorization for heart transplantation, benefits may be extended if the services or supplies otherwise would qualify for benefits but for the failure to obtain preauthorization. If preauthorization is not received, the appropriate preauthorizing authority as outline in [paragraph II.A.](#) under Policy is responsible for reviewing the claims to determine whether the beneficiary's condition meets the clinical criteria for the heart transplant. Charges for transplant and transplant-related services provided to TRICARE Prime enrollees who failed to obtain PCM referral and HCF authorization will be reimbursed only under Point of Service rules.

G. Benefits will only be allowed for transplants performed at a TRICARE or Medicare approved heart transplantation center. The contractor in whose jurisdiction the center is located is the certifying authority for TRICARE authorization as a heart transplantation center. Refer to [Chapter 11, Section 11.5](#) for organ transplant certification center requirements.

H. Claims for services and supplies related to heart transplantation through September 30, 1998, will be reimbursed based on billed charges. Effective October 1, 1998, heart transplantation will be paid under the DRG. Acquisition costs related to the heart transplant will continue to be paid on a reasonable cost basis and not included in the DRG.

I. Claims for transportation of the donor organ and transplant team shall be adjudicated on the basis of billed charges, but not to exceed the transport service's published schedule of charges, and cost-shared on an inpatient basis. Scheduled or chartered transportation may be cost-shared.

J. Benefits will be allowed for donor costs. Refer to [Chapter 3, Section 1.6L](#) for guidelines regarding donor costs associated with organ transplants.

K. Charges made by the donor hospital will be cost-shared on an inpatient basis and must be fully itemized and billed by the transplant center in the name of the TRICARE patient.

L. Acquisition and donor costs are not considered to be components of the services covered under the DRG. These cost must be billed separately on a standard UB-92 claim form in the name of the TRICARE patient.

M. Transportation of the patient by air ambulance may be cost-shared when determined to be medically necessary. Reference [Chapter 7, Section 2.1](#).

N. For beneficiaries who reside in TRICARE regions, the issuance of a Nonavailability Statement (NAS) shall be in accordance with direction of the Lead Agent.

O. When a properly preauthorized transplant candidate is discharged less than 24-hours after admission because of extenuating circumstances, such as the available organ is found not suitable or other circumstances which prohibit the transplant from being timely performed, all otherwise authorized services associated with the admission shall be cost-shared on an inpatient basis, since the expectation at admission was that the patient would remain more than 24 hours.

IV. EXCLUSIONS

A. Benefits will not be paid for:

1. Expenses waived by the transplant center (e.g., beneficiary/sponsor not financially liable).
2. Services and supplies not provided in accordance with applicable program criteria (i.e., part of a grant or research program; unproven procedure).
3. Administration of an unproven immunosuppressant drug that is not FDA approved or has not received TRICARE approval as an appropriate "off label" drug indication. Refer to [Chapter 7, Section 7.3](#) for TRICARE Policy requirements for immunosuppression therapy.

4. Pre- or post-transplant nonmedical expenses (e.g., out-of-hospital living expenses, to include hotel, meals, privately owned vehicle for the beneficiary or family members).

5. Transportation of an organ donor.

B. Bridge transplantation, which is the practice of using an artificial heart or an assist device until a donor heart becomes available. Assist devices when used for bridge to transplantation are considered unproven. Refer to [Chapter 3, Section 5.3](#), regarding coverage of ventricular assist devices for uses other than bridge to transplantation.

C. Implantable devices intended for temporary mechanical circulatory support as a bridge to cardiac transplantation are considered unproven and may not be cost-shared. For exception to policy see below under EXCEPTIONS [paragraph V.C](#). Refer to [Chapter 3, Section 5.1](#) regarding coverage of ventricular assist devices for uses other than bridge to transplantation.

D. Services, supplies or devices, even those used in lieu of the transplant, when determined to be related or integral to an unproven procedure, may not be cost-shared (see [Chapter 8, Section 14.1](#), for guidelines on determining coverage for related services).

V. EXCEPTIONS

A. Services and supplies for inpatient or outpatient services that are provided prior to and/or after discharge from hospitalization for a heart transplantation performed in an unauthorized TRICARE or Medicare heart transplantation center may be cost-shared subject to applicable Program policy. Pre-admission services rendered by an unauthorized transplant center may also be cost-shared subject to applicable program policies. These exceptions are also applicable to heart transplantations performed prior to November 7, 1986.

B. Heart transplantations performed on an emergency basis in an unauthorized heart transplant facility may be cost shared only when the following conditions have been met:

1. The unauthorized center must consult with the nearest TRICARE-approved center regarding the transplantation case; and
2. It must be determined and documented by the transplant team physician(s) at the approved center that transfer of the patient (to the approved center) is not medically reasonable, even though transplantation is feasible and appropriate.

C. The HeartMate® IPLVAS is intended for temporary mechanical circulatory support for transplant candidates in nonreversible left ventricular failure as a bridge to cardiac transplantation. The intent of the HeartMate® IPLVAS therapy is to provide hemodynamic support while awaiting transplantation. This device is intended for long-term support until a donor heart is available. Bridge to cardiac transplantation utilizing the HeartMate® IPLVAS may be cost-shared only when the following conditions have been met:

1. There is written evidence that, at the time of implantation of the HeartMate® IPLVAS device, the patient had received unrestricted approval for cardiac transplantation from a TRICARE or Medicare approved transplantation facility.

NOTE: Approval by the local facility transplantation committee in no way guarantees approval for cardiac transplantation by TRICARE.

2. On therapeutic doses of cardiac inotropic medications.
3. On an intra-aortic balloon pump (if possible).
4. Left atrial pressure or pulmonary capillary wedge is equal to or greater than 20 mm Hg with either a systolic blood pressure equal to or less than 80 mm Hg or b. Cardiac index of equal to or less than 2.01/min/m².

D. Subject to meeting criteria outlined above under EXCEPTIONS [paragraph V.C.](#) for implantation of the IPLVAS, cost-sharing will be allowed for medically necessary and appropriate services and supplies directly related to the operation, use, and removal of the HeartMate® IPLVAS.

VI. EFFECTIVE DATE

A. This policy is effective for services and supplies related to a heart transplantation procedure that was performed on and after November 7, 1986.

B. September 30, 1994, for the HeartMate® Implantable Pneumatic Left Ventricular Assist System (IPLVAS).

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